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Mailed: June 5, 2002

Louis Gubinsky
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2100 Pennsylvania Ave., N.W.
Washington, D.C. 20037-3202

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,637,994

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,637,994, which claims the medical device LIPOSORBER® LA-15 and a method of making such a device, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 5 years.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of May 8, 1998 (63 Fed. Reg. 24557) 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,995 - 277) + 1,603 \\ &= 2,462 \text{ days}\end{aligned}$$

Since the regulatory review period began April 18, 1986, before the patent issued (January 20, 1987), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). (From April 18, 1986 to January 20, 1987 is 277 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

The five year limitation of 35 U.S.C. § 156(g)(6)(A) applies in the present situation because the patent was issued after the date of enactment of 35 U.S.C. § 156. Since the period of extension calculated under 35 U.S.C. § 156(c) for the patent cannot exceed five years under 35 U.S.C. § 156(g)(6)(C), the period of extension will be for five years.

The 14 year limitation of 35 U.S.C. § 156(c)(3) does not operate to further reduce the period of extension determined above.

If issuance of the certificate of extension occurs, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,637,994
Granted:	January 20, 1987
Applicant:	Nobutaka Tani, et al.

Owner of Record: Kanegafuchi Kagaku Kogyo Kabushiki Kaisha
Title: Adsorbent and Process for Preparing the Same
Classification: 502/404
Product Trade Name: LIPOSORBER® LA-15
Term Extended: 5 years

Any correspondence from applicant with respect to this matter should be addressed as follows:

Preferably, by facsimile: (703)872-9411

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

Telephone inquiries regarding this communication should be directed to the undersigned at (703)
306-3159.

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